

**K992650 AIRIS, AIRIS II**Oct 8, 1999  
63 days to decisionK992650 · Product code: **MOS** · Radiology  
Source: <https://www.510kdatabase.net/k992650/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Coil, Magnetic Resonance, Specialty (MOS)
Date received	Aug 6, 1999
Decision date	Oct 8, 1999
Days to decision	63 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hitachi Medical Systems America, Inc.</b>
Location	Twinsburg, OH, US
Contact	JAMES JOCHEN ROGERS
510(k) history	100 submissions · 100 cleared · 1991-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k992650/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 16, 2026